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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,182	VARGEESE ET AL.	
	Examiner	Art Unit	
	PAUL V WARD	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 54-70 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 54-70 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 54, 55, 56, 58, 62, 65-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54-56 and 58 are rejected for using the term "non-nucleoside" or "non-nucleotide", "chemical linkage" and terminal chemical group. The terms are vague and indefinite, and are not defined by the claim. Additionally, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, the claims fail to particularly point out the identity of the component described as "chemical linkage" and "chemical group". The current claim language is drawn to an activity or desired property of a compound. This language does not particularly or distinctly provide sufficient clarity regarding the structural/formulaic/nomenclatorial identity of the chemical core applicants intend to represent as a component of the compound articulated in the claims.

Claim 58 recites the relative term "conditions suitable", which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Additionally, Claim 58 recites "claim 1". This is a dependent claim that depends

from a cancelled claim. Further, the underscore ("_") should be removed from the claim.

Claim 62 is rejected for using the term "abasic moiety". This term is vague and indefinite.

Claims 65-70 recite the limitation "said abasic succinate", "said adenosidne succinate", "said cytidine succinate", "said guanosine succinate", "said thymidine succinate", and "said uridine succinate". There is insufficient antecedent basis for these limitations in the respective claims.

Response to Arguments

The following is in response to the amendment filed October 17, 2003. An action on the merits of claims 54-70 is contained below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi, in view of Nelson, both previously cited.

Applicant claims chemical entities from which oligonucleotides can be synthesized, for example nucleic acids, nucleosides, or nucleotides, and in

particular entities with an acid labile protecting group such as trityl groups, linked via a N-(6-aminohexyl)-3-aminopropyldimethoxysilane linker to a solid support, such as controlled pore glass. Applicant further claims methods to make such compounds, including methods that specify the loading capacity of the solid support, namely from about 50 to about 100 μmol/gram of solid support, or from about 75 to about 85 μmol/gram of solid support.

Kobayashi teaches physiologically active substances that are immobilized on an inorganic support, by treating the inorganic support with an aminoalkylalkoxysilane. (See Abstract). In column 1, lines 55-58, Kobayashi discloses that the inorganic carrier or support can be porous glass, silica gel, colloidal silica, alumina, etc. Additionally, Kaboyashi teaches that the aminoalkylalkoxysilane used to treat the inorganic carriers can be N-(6-aminohexyl)-3-aminopropyltrimethoxysilane. (See col. 1, lines 59-64). Further, Kaboyashi teaches that "the aminopropylakloxysilane mediates chemical bonding between the inorganic carrier or support and the physiologically active substance". (See col. 2, lines 26-29).

Kobayashi does not explicitly teach that the physiologically active substance can be a nucleoside, nucleotide or a chemical entity from which an oligonucleotide can be synthesized. In addition, Kobayshi does not specifically teach that the loading capacity of a solid support or the length of the spacer.

Nelson, teaches that novel multifunctional solid support reagents that are useful in solid phase oligonucleotide synthesis. (See Abstract). Nelson teaches that the reagent is linked to a solid such as a controlled pore glass and

aklylamine. (See col. 2, lines 35-44). In column 4, lines 1-22, Nelson teaches that the oligonucleotide can be linked to the solid support via an alkoxysilane linker, namely MF-CPG, wherein the length of the spacer is 18 atoms in length. (See Figure 1).

It would have been obvious to one of ordinary skill in the art to use any chemical entity from which an oligonucleotide can be synthesized as the physiologically active substance immobilized on an aminoalkyalkoxysilane treated inorganic support, as taught Kobayashi, by including a spacer molecule as suggested by Nelson with a reasonable expectation of success. The motivation to do so is provided by Nelson who teaches the usefulness of including a spacer having a molecule length of 18, and the teaching of Kobayashi of adapting the aminopropylalkoxysilane linker. Thus, the combined references teach and suggest all of the claim limitations. Therefore, the claimed invention as a whole is obvious over the combined teachings of the prior art.

Applicant's arguments filed October 17, 2003, have been fully considered but they are not persuasive.

In response to Applicant's argument that there is no suggestion to combine the references since applicant uses a spacer 12 atoms in length, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F2d. 1071, 5 USPX2 1596 (Fed Cir. 1988)

and In re Jones, 958 F.2d 347, 21 USPX2d 1941 (Fed. Cir. 1992). In this case, Kobayashi teaches physiologically active substances that immobilized on an inorganic support, by treating the inorganic support with an aminoalkylalkoxysilane. (See Abstract). Kobayashi teaches that the inorganic carrier or support be porous glass, silica gel, colloidal silica and alumina, and that the aminoalkylakoxysilane used to treat the inorganic carriers can be N-(6-aminohexyl)-3-aminopropyltrimethoxysilane. (See col. 1 lines 55-64). Nelson teaches novel multifunctional solid support reagents that are useful in solid phase oligonucleotide synthesis. (See Abstract) Nelson, in column 2, lines 35-44) teaches that the reagent is linked to a solid such as controlled pore glass and alkylamine, and that the oligonucleotide can be linked to the solid support via an alkoxysilane linker. Moreover, Nelson teaches a molecule with a long spacer (See. Fig 1). Since the combined references teach and suggest all of the claim limitations, the claimed invention as a whole is obvious over the combined teachings of the prior art.

Conclusion

Claims 54-70 are pending. Claims 54-70 are rejected. No claims are allowed.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The required appeal fee must accompany the Notice of Appeal.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

pvw

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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